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New product testing and the utilization of user expertise: Evidence from the Pharmaceutical industry

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Abstract

A significant and often neglected obstacle in new product development is the testing and approval process in the late stages of development. The testing process has primarily been observed as an in-house decision process, however, in many industries products undergo extensive testing before market launch where external stakeholders play a key role. Users are often integrated in testing of new product candidates, and supply valuable knowledge to developers by testing the new product in natural business settings. As especially high-tech products are closely linked to related services and usage patterns, utilization of users input to not only product functionality, but also the related services and usage patterns are relevant.
This study contributes to the literature on these crucial phases of late stage product development, by exploring developers' utilization of the knowledge and experiences generated by users in product testing. Further, the important user network in high-tech product testing may likely be globally dispersed, and the mean of communicating between user and producer in the testing process are therefore tested.
A dataset of 395 site-representatives are applied to study the knowledge generated and shared by medical sites and Pharmaceutical producers in late stage product development.
The results show, that information regarding usage patterns and product related services are more difficult to transfer between user and developer, than issues directly related to the product. Further, with a dispersed user network a positive effect is observed on the mean to communicate directly as issues occur. The effect of virtual communication is therefore stronger than traditional face-to-face interaction patterns.

Introduction

The down-stream development processes, such as prototype development, -testing and market introduction, are important measures in NPD and the later market performance. It is in these late stages new technologies are developed into products, and are subject to critical tests before market launch (Cooper 2001; Barczak ét al. 2009). As firms' technological capabilities expand and more unique products are developed, the testing phases play a more central role in NPD processes (Dolan and Matthews, 1993). This is further emphasized, as many technologies are often highly connected to related services relevant for the new product (Tukker and Tischner 2006; Mont 2002; Morelli 2006). As many products are closely linked to related services, users role becomes even more prevalent in the critical testing processes. Further, usability patterns are increasingly important, as usability measures such as users convenience and practical application of a product can have huge influence on market performance besides the products concrete effect (Bevan 1995, MaGuire 2001, Alonso-Rios ét al. 2010). The testing phases in late stage development can thereby supply user input to product functionality, but also product related services and usability patterns of the new product.

This is especially the case in high-tech industries, as users integrated in the development process are often highly skilled and knowledgeable. High-tech users will often have in-depth knowledge about the market, and therefore expertise concerning the product area, usage patterns and related service required for product application. This could be knowledge related to issues such as the workforce required in managing the product, access to the new product and attitude to product profile in the market. By integrating the new product in daily business processes, users can apply the product and supply firms with valuable knowledge. This knowledge could then result in prototype adjustments, spin-off products, new market applications or segmentation differentiation.

There is a gap in extant literature in exploring the organization and optimization of the crucial testing phases, and here the industry's utilization of user input in these late stages of development. This paper seeks to meet this gap by exploring the information processing dynamics between users and producers in the testing processes before market launch. Producers have a unique opportunity to tap into knowledge generated by competent users with experiences in the market and product through their participation in product testing. We therefore explore how difficult product related aspects are generated by the users and then shared with the producer in relation to service and usability related issues.

As users are most likely located in multiple global locations, the effect of communication mean should also be considered in relation to the difficulty of generating and sharing knowledge between user and product during testing phases. This especially apply in high-tech industry product testing, where industry have an interest in integrating professional users with expertise in the product area in the testing process. These users may therefore be dispersed, both from each other and from firm representatives, and the way of interaction such as face-to-face meetings, virtual or written means is considered in this study.

To investigate the difficulty of generating and sharing knowledge between user and producer by topic area focus is drawn to a high technology driven market – drug development. The Pharmaceutical industry is an interesting case of down-stream partnerships, as future users are directly integrated in the processes of product development. New product prospects undergo extensive testing phases (clinical trials), which are conducted by medical sites such as private clinics, health centers, hospitals, and academic medical centers. The physician's expertise within the therapeutic area, as well as their link to patients, is a valuable asset for the Pharmaceutical industry (Getz and Zuckerman 2010). The patients can be defined as the end-user in relation to new drugs, however, as the medical sites are those whom prescribe drugs and therefore make the main decisions on product type and usage, these are defined as

the user in this analysis. We test our theoretical derived hypotheses on a sample of 395 responses from medical sites. The difficulty of generating and sharing knowledge between user and producer during testing phases is analyzed by applying a Rasch Scale model (Item Response Theory).

The paper proceeds as follows. First the conceptual model is presented, which leads to the hypotheses. Second, the case and data collection is presented, as well as the method applied in the analysis. Third, the results of the analysis are presented and hereafter discussed, and lastly conclusions and managerial implications as wells as limitations and further research.

Conceptual model and hypotheses´

User input in new product testing

Product testing is a central element in late stages of development. Especially in high-tech industries product testing is a key measure, as the often time-consuming research and early development phases are now being tested for the market. In NPD studies the primary goal of the testing phases is defined as product functionality, and market intelligence measures before launch (Cooper 2001; Barczak ét al. 2009). Here the users play a central role, as they are integrated in these late stages of development to participate in the product testing processes. Users are applied in the prototype testing in the late stages of development often conducted for marketing purposes (Thomke and von Hippel, 2002; Cooper 2001), as well as creating early adopters of the product and influence opinion leaders (van Eck, Jager and Leeflang, 2011; Chiesa and Frattini, 2011).
However, the testing processes can supply industrial development processes with more than merely prototype testing for functionality, and marketing measures (Dolan and Mathews 1993). As new products are being applied in natural business settings, users can test new products, but also generate information about product related services (Tukker and Tischner 2006; Mont 2002; Morelli 2006), and usability patterns (Bevan 1995, MaGuire 2001, Alonso-Rios ét al. 2010). This especially applies in relation to more complex products, where the integration of a product in daily business processes may supply information, which is difficult to duplicate in in-house alpha testing programs (Dolan and Mathews 1993).
In product testing processes users can thereby supply information about product functionality and then related services (Tukker and Tischner 2006; Mont 2002; Morelli 2006). In industries such as car manufacturing, users can supply information about the functionality of the car, but applying the car in a natural setting can also generate information about services related to the product, such as maintenance issues (Williams 2006).
Besides product functionality and related services, also usability patterns are relevant in the testing phases. Usability is often mentioned in relation to the increasing focus on design measures in new product development (Bevan 1995, MaGuire 2001). Testing for usability measures requires application of the product in use, and usability is therefore often referred to context-of-use measures (Bevan 1995, MaGuire 2001, Alonso-Rios ét al. 2010). Context-of-use by applying new products to users natural business settings can thereby supply valuable information about usability of the new product beyond basic functionality issues. Usability issues are relevant in various industries such as medical devices where eg. ostomy care products, are not only tested for product effect, but also patient convenience in the use. Or IT products such as recent developments of tablets where not only product functionality, but also usability measures can be tested in use, such as the user interface, and product size, dimensions etc..

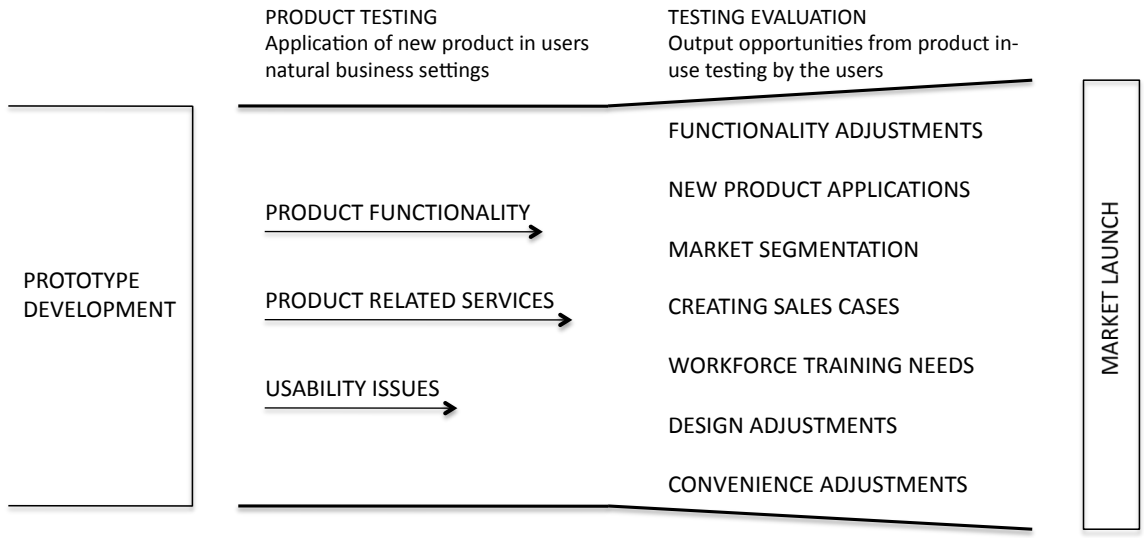

Figure 1: Late stage product development opportunities

The testing phases of new product development can supply producers with valuable product-in-use information concerning product functionality, product related services and usability patterns. The users ability to share their information is therefore a valuable asset in product testing optimization. Differentiating users knowledge sharing ability in product testing concerning product functionality, related services and usability patterns can thereby support further understanding of the utilization of a key stakeholder in product testing, which leads to the following hypothesis:

Hypothesis 1: *Direct product related aspects are easier generated and shared than product related service-, and usability related issues.*

Communication mean and knowledge sharing ability

In order to utilize the information gained by users during product testing channels of communication needs to be established between user and producer. Previous studies on information processing have pointed to the balance between co-location of partners vs. cross-distance communication means such as web-based solutions (Song ét al. 2005, Bathelt and Turi, 2011; Song ét al. 2007). A characteristic in the collaboration between producers and their network of professional users is that these actors are not located at the same place as the in-house staff. Users in general and especially when qualified by their professional profile are likely to be located in many global locations. When questioning the knowledge transfer process in the crucial testing processes the dispersed relationship should be considered, and therefore the means of communicating between user and producer.
Communication mean is defined in three formats: 1) Communication where actors are at the same location at the same time, which implies a traditional face-to-face setting. 2) Communication across space, but at the same time, which can be direct communication via a virtual media such as conference calls, web conferences etc. 3) Communication neither in time nor space, which can define written communication in reports, emails etc.

Face-to-face communication means. Proximity is often mentioned as an influential factor, as close physical location can stimulate flow of knowledge (Gulati, 1998; Rosenfeld, 1997;

Hoegl and Proserpio, 2004) as both formal and informal interactions can occur (Porter, 1998; Gulati, 1998). The co-location of partners also stimulates a common frame of reference and belief system, which is stimulating to information processing (Song éy al- 2005; Grant 1996; Berchicci and Tucci 2010).
Continuous co-location of users and producers is not applicable in product testing, as the product is to be tested in natural business settings. However, in the planning of product testing producers can arrange for face-to-face meetings with users, which can occur at the firm, on site or at professional settings such as technological or industry related conferences. Through these face-to-face meetings the dynamics of co-location can be applied, as users can communicate testing experiences directly with the producer. Thereby both formal feed back and more informal measures can be transferred, which leads to the following hypothesis:

H2A: If collaborating partners have the means to communication directly with each other both in time and space (Face to Face), this will have a positive effect on users knowledge sharing ability with producers.

Communication direct across space. Collaboration across distance is increasing with globalization and it becomes more relevant to also explore communication, which may occur across space (Baker 2002, Powell ét al., 2004, Bathelt and Turi, 2011). Previous literature is inconsistent in consequences of communication in global settings, where actors communicate via virtual media. Some studies emphasize the social relations generated by being co-located, which is challenged when actors are dispersed over distance (Hoegl and Proserpio, 2004). Other streams of literature point to the opportunities created by technological development, and therefore the possibilities of generating social connection via virtual media (Bartlet and Turi, 2011; Hoegl ét al., 2007; Schmidt, Montoya-Weiss and Massey, 2001). It is here emphasized that virtual media can generate opportunities for partners to communicated directly and therefore give feedback and agree on a common understanding concerning a certain issue, which compensate for the lack of co-location (Baker, 2002; Crampton, 2002). This study builds on this perspective emphasizing feed back processes in knowledge sharing and therefore the opportunity to communicate directly at the same time, but across space, and hypothesize:

H2B: If collaborating partners have the means to communication directly with each other in time (direct across space), this will have a positive effect on knowledge sharing ability.

Written communication. In line with the previous two hypotheses, which argue for a positive effect of actors to be able to communicate either directly in time and space, or directly in time, this study predicts that written communication is challenging to knowledge sharing ability. When controlling for face-to-face, and virtual communication, we predict a negative effect of written communication means, and hypothesize:

H2C: If collaborating partners have the means to communication neither in time or space (written), this will have a negative effect on knowledge sharing ability.

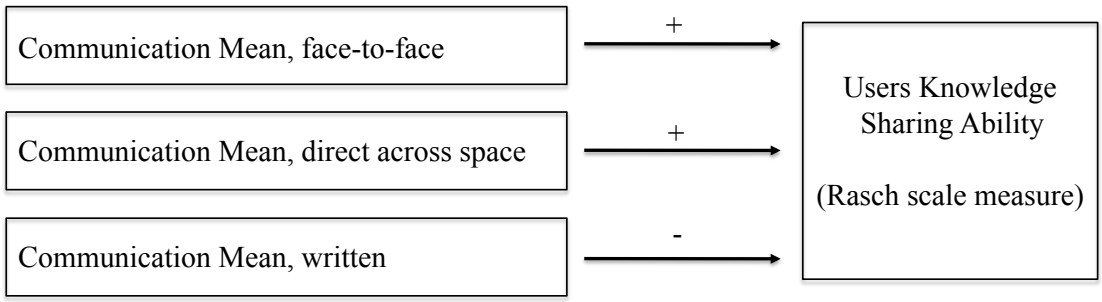

Figure 2. Hypotheses (research model)

Research method

Pharmaceutical product development is an industry, which is highly dependent on their performance during product testing. Potential new products undergo extensive testing phases following strict clinical trials, which are conducted by medical sites such as private clinics, health centers, hospitals, and academic medical centers. During these trials pharmaceutical producers collaborate with users, whom have the direct access to patients, as well as physician's expertise in the therapeutic area (Getz and Zuckerman 2010). Companies develop trial protocols and manuals for product use, which sites apply in the clinical trials. Feedback from the sites on safety and efficiency of the new products are then reported back to the company and entails the application to the regulatory authorities for gaining approval of the new product to the market (Hathaway ét al. 2009). Physicians are thereby integrated in the development of new products before market launch, thus presenting an example of how users in some industries are a central player in the down-stream processes.
As the medical sites are the main decisive partners on the market, by being responsible for prescribing drugs and guiding patients (end-users) on product usage, the medical sites are in this paper referred to as the professional users.

Data collection

To test the hypotheses a study among medical sites participating in clinical trials in pharmaceutical drug development processes were carried out. These site representatives are difficult to locate and identify, as there are no public listings of these sites. A contact list to clinical sites was developed through previous studies including industry respondents. Here Pharmaceutical partners were asked to supply contact information to their site stakeholders, which amounted to a list of more than 1500 functioning clinical sites. This unique list of otherwise enclosed information was applied in this study and from this a questionnaire developed. 395 site representatives responded to the questionnaire, which therefore supply a substantial sample size, and a satisfactory response rate of approximately 25 %.
In order to obtain a rich measure for *users ability to share knowledge with the producer*, the question were divided in to 11 sub-questions covering 11 topic areas, as identical 4 point Likert scales. The aim of this study is to explore if some topics are more difficult to generate knowledge about and share between user and producer. Three topic areas are explored. 1) Issues related directly to the product's functionality, which in the case of Pharmaceutical product development is topics related to the safety and efficacy of the new drug. 2) Issues concerning related services, which in drug development refer to the management of the drug in the clinical practice. Service issues concerning the application of the new drug in practice,

and related to a medical clinic or hospitals administration issues. 3) Usability issues, which in drug development refer to the end-users responds to design related topics.
In the development of the topic items relevant for the pharmaceutical testing process, the study guidelines, which is a manual to the users during the testing process, was studied. The study guidelines focus primarily on the product functionality, as the prime goal is testing for safety and efficacy in order to acquire regulatory approval. However, as this study wants to explore users knowledge generation and sharing beyond product functionality other topic areas was explored. Here the clinical practice guidelines were studied, as these guidelines are applied after a drug has been approved. Clinical practice guidelines are a written document applied in the practical application of a drug by the clinical personal at hospitals or other health centers. The post-market launch perspective was applied to understand which topic areas were relevant for the users in practice. These guidelines include issues of product related service, which is relevant for the application of the drug in practice, as well as usability related issues related to the end-user (patient) comfort. The topic items were listed randomly in the actual questionnaire as listed in table 1.

Table 1. Topic items regarding the drug development testing divided by product, service or usage topic items

Item No.	Question content	Issue item
1	Drug side effects	Product
2	Administration of the new drug (e.g. taken with meal, taken in the evening, on empty stomach etc.)	Usage
3	Concomitant drug interactions	Product
4	Delivery form (tablet, capsule, injection etc.)	Usage
5	Dosage of new drug	Product
6	Cost effectiveness of new drug	Service
7	Patient access to the drug	Usage
8	Risk/benefit from intervention	Product
9	Clinical skills necessary for successful drug administration	Service
10	Workforce required for drug administration	Service
11	Patients and professionals reaction to branded name	Service

Method

The papers method is twofold. To answer hypothesis 1 a Rasch scale model is applied in order to make a diverse scale of users ability to share knowledge with the producer. Hereafter the Rasch scale measure, which will be a result of the Rasch analysis of hypothesis one, will be applied as the dependent variable in a regression analysis.

Rasch scale modeling

To study hypothesis 1 and therefore how users ability to share knowledge with the producer may be differentiated by topic area, Rasch scale modeling is applied, (Rasch, 1980; Bond and Fox, 2001) which is part of the item response theory, IRT (Singh, 2004; de Jong ét al., 2008). Instead of focusing on dependent and independent variables, item response theory focus on

measuring related items and their positioning on a scale (Singh 2004). A Rasch scale model is applied to evaluate the relationship between items measured by probability statistics modeling (Singh 2004; Rasch 1980).
The loadings of the respondent's answers to the 11 item areas, measured on a 4 point likert scale, are entered into the Rasch model. The Rasch score then defines the ability of the site respondent to contribute with information on the same scale as the item difficulties. The scale output is thereby an illustration of the item/person relationship. The person measure on the scale illustrates which sites are able to provide which information to the producer. The item measure defines an order of the items by assigning difficulty values to the 11 items defined in table 1. The scale thereby assigns a relative measure on a common continuum defining how difficult a certain item topic is to share relative to the other item topics. The measure can thereby support an analysis of users ability to share knowledge by assigning different difficulties of sharing knowledge from user to producer.

The interest point of this paper is the relationship between the items, but the scale of persons is related and contributes with indications of model fit (Bond and Fox 2001). If the item-person scale does not correspond, it implies that the chosen items does not describe the issue area in question, which in this case is person's ability to share knowledge. Item fit statistics thereby supply information concerning the fit between the Rasch scale model and the observed data. Such infit/outfit measures can be identified in the analysis and will be elaborated on in the result section.

Measures

To validate the result of the Rasch scale model and therefore also hypothesis 1 a regression model is developed. Further, a regression model is applied to explore hypothesis 2A-2C, and therefore the effect of communication mean on users ability to share knowledge with the producer.

Dependent variable. Besides presenting a scale, which makes it possible to relate topics items directly to each other, the Rasch method also produce a single measure representing the scale. The Rasch measure can be defined as the likelihood of a certain item topic to score high in the likert scale answered by the respondents (Bond and Fox, 2001). The measure therefore integrates a loading of the item topics in an overall measure and represents a more differentiated measure, than if a mean of all item areas was developed. This measure can be entered into a regression model, to further validate the scale results, and test the effect of communication mean on the scale outcome. The Rasch scale measure produced from a scaling of users ability to share knowledge with the producer is thereby applied as the dependent variable in a regression analysis.

Independent variables. To test the effect of communication mean on users ability to share knowledge with the producer, three groupings of communication means are applied:
1) *Communication mean – Face-to-face (F2F)*. F2F communication between user and producer includes meetings where the actors have an opportunity to meet directly with each other and discuss development related issues. Respondents were asked to indicate on a three point likert scale how often they have; *Sponsor visits at site* (face-to-face communication). Here the sponsor (pharmaceutical company) visit the site and speak directly with the site representatives. Or *Off site meetings and conferences*, which included industry specific conferences or related forums where site- and pharmaceutical representatives meet.
2) *Communication mean – direct across space.* Communication across space is here defined as meetings where user and producer can communicate directly with each other in time, but

not present at the same location. The respondents were here asked to indicate on the same three point likert scale how often they have; Telephone conversations/conferences calls etc., or Web-based meetings. In the case of clinical trials, medical sites are often in multiple global locations, and the sponsor company therefore collaborates with partners across the world. Direct across space communication is therefore defined as telephone conferences and web-based meetings, where actors are not at the same location, but have the opportunity to communicated directly and therefore discuss, reflect and give direct feed-back.
3) *Communication mean – Written.* Written communication is defined as a more classical communication mean, where user and producer communicate via written means. Respondents were here asked to indicate how often they communicate by; *Email exchange* or *General written communication*. In clinical trials much documentation about the results of the trial is documented in reports, which is then transferred from site to the firm.

Controls. Two types of control variables are applied in the model: 1) Variables related to the user characteristics, 2) Variables related to the collaboration process between user and producer:
1A) *Job role of site representative* is applied as a control measure, which characterizes the users role, as site representatives in clinical trials can be doctors, nurses or administrative staff. We categorize the job role in two groupings: Medical users and supporting staff. This dichotomous categorization control for the type of knowledge and resources the user represents, as the doctors will have most insights into the specific product area.
1B) *Experience of users* is also applied as a control variable, as this may influence the medical staffs´ ability to share their knowledge from clinical trial participation. Users experience is measured in years of clinical trial participation and therefore as a numerical measure.
2A) *Personal relations.* It is a well-known factor in the industry that the same sites may be applied continuously. This is both due to the site and individual doctors role in the market, which is especially important if they are considered as a key opinion leader. Or it may be due to the personal relations established over time, which therefore make the sponsor-site relation important to both partners. In studying the effect of communication mean on knowledge sharing ability, we therefore also control for the personal relationships between site and sponsor.
2B) *Post trial meetings.* Drug development resembles the stage gate model to a high degree (Cooper, 2001), as each clinical trials result in a go/no go decision, and therefore end of a trial and collaboration with a medical site. However, producers may interact post trial termination, and we control for post trial interaction between user and producer, and therefore for non-targeted variance in the post trial phases.

Results

To address hypothesis 1 a scale-modeling tool is applied in order to explore the difficulty of sharing knowledge between user and producer by topic area. The 11 topic items (Table 1), which are categorized as topic items related to product functionality (safety and efficacy), related services or usability issues are entered into a Rasch scale model. The results of the Rasch analysis is in the following presented in two output measures; 1) *Fit statistics*, which illustrate the fit of the scale and therefore if the 11 topic items cover the knowledge gained and shared between user and producer. 2) *Item difficulty*, which scale the difficulty of generating and sharing knowledge concerning the 11 topic items between user and producer.

Fit statistics

Fit statistics are computed in the Rasch analysis and supply information concerning the fit of the data in relation to the Rasch output map. The mean square values should have an expected value around 1, but values will exist above and below this. If the MNSQ *infit* values are significantly lower than 1 some dependencies are present in the data, and if higher than 1 then some noise should be considered in the model (Linacre 2010). Further, MNSQ *outfit* level significantly lower than 1 also imply dependency in the data, while an MNSQ *outfit* level significantly above 1 indicate that there is some unexpected outliers in the chosen variables.

Table 2. Fit statistics, Rasch analysis (Winstep output)

Item No.	Description	Issue item	Difficulty	MNSQ	
				Infit	Outfit
6	Cost effectiveness of new drug	Service	1.57	1.14	1.15
11	Patients and professionals reaction to branded name	Service	1.26	1.19	1.22
7	Patients access to the drug	Usability	.80	.90	.87
10	Workforce required for drug administration	Service	.41	.77	.75
4	Delivery form (tablet, capsule, injection etc.)	Usability	.07	1.03	1.09
2	Administration of the new drug (e.g. taken with meal, taken in the evening, on empty stomach etc.)	Usability	-.18	.91	.96
9	Clinical skills necessary for successful drug administration	Service	-.27	.81	.78
5	Dosage of new drug	Product	-.44	.98	.96
8	Risk/benefit from intervention	Product	-.59	.93	.87
3	Concomitant drug interactions	Product	-.74	.90	.90
1	Drug side effects	Product	-1.89	1.29	1.32

Difficulty: degree of users ability to share with producer reflected in the specific item.

A rule of thumb is a level within +/- .2 (.80/1.2) (Bond and Fox 2001). Item number 1 therefore shows some sign of both noise and outliers, and item 10 show tendency to dependency in the data. The MNSQ fit statistics for item 1 and 10 is however not substantially different than 1, and is both critical issues within the empirical area studied – clinical trials - and is therefore kept in the model. This should however be considered if specific conclusions about item number 1 or 10 is drawn isolated. As mentioned in the introduction we primarily observe the items as part of a grouping – clinical practice issues or product management issues – and as so the items with borderline fit statistics are kept in the model.

In item statistics the measurement method of the individual items can support reliability of the model, if the measurement items are alike. However, this can create some validity issues, which is better supported if the item measurements are different from each other (Singh 2004). In this study´ Rasch analysis the item measurements are alike and therefore the model reliable. However, the tradeoff can be an under-identifying power of the model, as the scale may not cover some issues. This can be observed in the model by the person measurements in the left side of the scale, which should be within the range of the item measures on the rights side of the model. If person measurements and item measurements are not in the lower part of

the model floor effects can be observed, and correspondent ceiling effects in the top of the model.
An over-representation of person items above the high difficult measure (Item 6, difficulty 1.57) can be observed, which suggest that the model is slightly under-represented. This is a limitation to the model, and should be considered in future research. This model indicates a clear pattern concerning the included item topics, but also point to the need of further development and inclusion of more item topics in future studies.

Item difficulty

Besides item 1 and item 10, which reflect some fit challenges to the model, the other nine items are well represented within the fit limits in the Rasch analysis. This indicates, that users generate and share relevant knowledge concerning product functionality, related services and usability issues by participating in test phases in NPD. The model illustrate that managerial issues are relevant to pursue in utilizing user capabilities. Users actually obtain knowledge concerning the late stage development process, which are not in direct line with their professional profile. The model reveal that the managerial issues are more difficult to transfer, which both can be due to the profile of the users, and the existing processes of perceiving and utilizing users resources.

Figure 1 illustrates the Rasch map generated by the Rasch scale-modeling program Winstep (Linacre 2010). On the left side of the model the respondents are represented in relation to their answers to the 11 items. On the right side of the continuum the items are outlined in relation to each other.

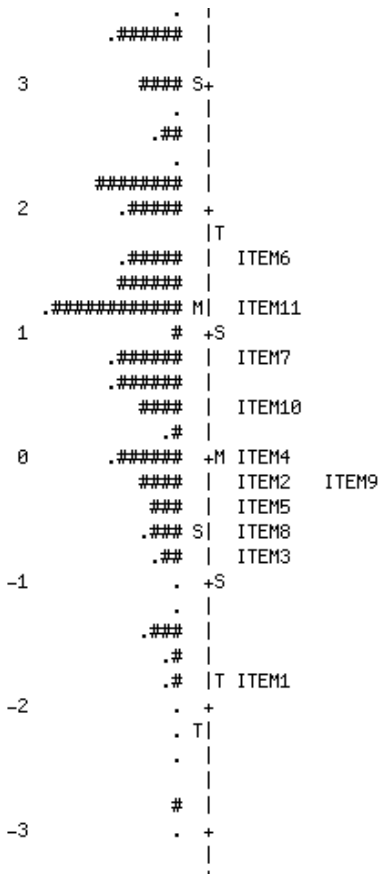

Figure 3. Item-person map, Winstep output

Overall there is a tendency for issues related to product functionality to be easier to generate and share than issues on related services and usability of the product. In the bottom of the scale shown in figure 2 items 1, 3, 8 and 5 can be observed. These 4 items all relates directly to the products functionality, and therefore the safety and efficacy of the new drug: drug side effects, drug interactions, risk/benefit from intervention and dosage of new drug. The bottom of the scale indicates, that the issues related to product functionality are easiest to transfer in relation to the other items measured on this scale.

The four item issues related to product functionality are therefore easier to generate knowledge about and transfer to the producer. The other 7 item issues, which are more difficult to transfer, all relate to either service or usability issues. In the end of the continuum, and therefore representing the most difficult issues to generate knowledge about and transfer to the producer, is item 6 and 11. Item 6 - cost effectiveness and item 11 – reaction to branded name, are both related service issues, which are highly relevant for the final market launch. Though, these issues are not crucial to the regulatory approval, and therefore not required to tests for in the clinical phases. These issues are therefore not a standard measure in the study guidelines, and also not in the clinical practice guidelines, but central issues in the application of the drug at hospitals and clinics.
Also in the most difficult end of the scale item 7 - Patients access to the drug (service) and item 10 - workforce required for drug administration (usability) can be observed. These issues are also not requirements according to the regulatory approval, and therefore related to safety and efficacy. But they are important to clinical practice and can therefore be applied in clinical practice guidelines.
In the middle of the continuum item 2, 4 and 9 can be observed. These three issue areas (Administration of drug, Delivery form and clinical skills necessary) does not directly apply to the product functionality and is therefore not prime topics in the study guidelines. However, these issues are all highly relevant to clinical practice after a drug have been approved, as is therefore mentioned in the medical sites clinical practice guidelines applied in the application of the final drugs.
The Rasch scale outcome illustrates a pattern, which relates to the conceptual categorization of topics in product, service and usability. Hypothesis 1 stating that issue items related directly to product functionality are not as difficult to generate and transfer between user and producer, as service related and usability issues, can be confirmed. The scale analysis illustrates that service and usability topics are more difficult to generate and transfer by the users, than issue related to product functionality.

To test this result further, the Rasch scale measure is applied in a regression analysis where the effect of communication mean are explored.

Knowledge sharing ability and communication mean

As global activities increase, so does the communication across large distances. This have brought by many technological opportunities in which partners can communicate directly with each other even though not in the same locations, such as tele- and web conferences (Baker 2002, Bathelt and Turi 2011). This issue can be defined as a differentiation among TIME and SPACE, as partners may communicate at the same time, but across geographical space. We follow this division of communication mean in this study, as clinical trials have experienced a great globalization in the last years, and therefore often have multiple sites on many global locations integrated in one trial. We therefore make three variables in relation to communication mean in order to test this issue further: 1) Direct communication, face-to-face. 2) Direct communication, direct across space. 3) Written communication.

Table 3. Results for regression analysis of the effect of communication mean on users ability to share knowledge with the producer.

		Model 1		Model 2	
Predictors		**B**	***t-value***	**B**	***t-value***
Control variables					
Personal relations		.93**	2.44	.79**	2.07
Post trial efforts		.76*	2.68	.48*	1.67
Job role		.36	1.59	.66***	2.93
User experience		-.00	-.11	.00	.11
Independent variables					
Communication mean	Face to face			.49*	1.90
	Direct across space			.97***	3.52
	Written			-.03	-.08
R^2			.047		.119
Adjusted R^2			.036		.101
df			333		330

**=p < 0.1, **=p < 0.05, ***=p < 0.01, n = 337*

The regression analysis reveals that written communication does not have a significant effect on users ability to share knowledge. However, both face-to-face communication (Unst. coef. B: .49, *t:* 1.9) and communication across space (Unst. coef. B: .97, *t:* 3.52) have a positive effect, and we can thereby confirm hypothesis 2a and 2B. Notable is, that even though face to face communication means have a significant effect on the scale of knowledge sharing ability of users, the effect of direct communication across space is higher. Communication across space have a high *t* value, which supports studies of knowledge sharing across distance, and expands on previous studies claiming that proximity promotes social relations, which generate knowledge sharing. Global connections are possible in today's collaborative connections in new product development, as long as partners have the opportunity to communicate direct in time, and therefore as things occur. Face-to-face communication among global partners has the disadvantage, that issues are then discussed on a later point in time, when global partners have a chance to meet. This is also the case in drug development, as face-to-face interaction occurs, when Pharmaceutical companies visit the sites, or they have meetings off site, or at conferences. This can be useful and this papers result also show an effect of this mean of communication. But in a global collaboration framework, the communication means across space, but at the same time, and therefore via virtual means of communication, give partners the opportunity to give direct feed-back, and users to articulate ongoing reflections.

Discussion

This papers extended perspective on testing optimization builds on the perspectives on beta-testing by Dolan and Matthews (1993), and adds to traditional perspectives of product testing in NPD literature (Cooper 2001, Shaw 1988) where product functionality and marketing

measures is the prime goal. The results of the analysis show, that it is relevant to differentiate between product functionality, and then related services (which also include marketing measures) and then usability patterns. Users gain information about more than direct functionality issues, but also other measures, which is relevant for the producer in the further development, adjustment and launch of the new product. In the testing processes of the Pharmaceutical industry the processes is primarily build on formal information processing structures, where users are to gather information related to product functionality, which is required by regulatory authority before market approval. However, this study reveals that users gain information, which extends beyond the required safety and efficacy measures. These issues on related services and usability patterns are though more difficult for the user to share with the producer. The industry is therefore not optimally utilizing users expertise gained from intense integration in late stage development phases. This may be due to pressure on the time-consuming and costly trial phases (DiMasi and Grabowski 2007), which therefore are being optimized for regulatory purposes. This may however compromise valuable knowledge input related to the application of the product, design optimization and in general issues related to the testing process it self.

The results of the effect of communication mean on knowledge sharing ability further emphasis the importance of the relation between user and producer. No effects of written communication means on knowledge sharing ability was found, which is interesting as much information concerning clinical trials is transferred in written reports, templates etc. ready for regulatory review. The positive effect of both face-to-face and virtual direct communication illustrates the importance of being able to communicate directly with each other during product testing. In such settings informal information processing can occur, and therefore the sharing of knowledge, which go beyond product functionality issues. It was here interesting to observe, that previous arguments for the importance of co-location (Song ét al- 2005; Grant 1996; Berchicci and Tucci 2010) was challenged by and increased effect of communication means, where global actors could communicate directly when things occur. Communication means where actors can supply feed back and reflections during the process have a strong effect of knowledge sharing ability. In organization product testing in high-tech product development the means to which users can supply and discuss they experiences with the product in use is therefore important. Direct communication between producer and user can stimulate the output generated by producers in product testing.

These results are interesting in relation to the development of the testing processes in the Pharmaceutical industry. The expenses of clinical trials are continuingly increasing in the pharmaceutical industry even though more products are not entering the market (Kaitin 2010). There is therefore a common understanding in the industry that the extensive time-consuming and costly development process needs to be more effective. These motives have made pharmaceutical companies outsource previous in-house competences, such as site selection and data management, which are both closely connected to the relationship to trials, to a broker agent (Howells 2006; Hargadon and Sutton 1997; Bessant and Rush 1995; Gould and Fernandez 1998) The use of outsourcing to a broker agent in the late stage of drug development now often included CROs managing the direct relations to trial sites as companies outsource clinical trial processes in a full service partnership (FSP) (Getz and Zuckerman 2008; Bodenheimer 2000). It has been recognized that the integration of a CRO may generate savings on cost and time (Getz 2007; Kaitin 2010) as these organizations are specialized in the down-stream task of clinical trial management. There is however limited research focusing on the challenges the integration of a third part agent may course to the utilization of the users capabilities in down stream product development. The direct tie between sponsors and clinical sites may be jeopardized as the task of trial management are not perceived as a core competence and therefore moved to a third party agent. The flow of

unique knowledge obtained in the clinical trial phases may therefore be compromised in the new structures of drug development, which should be further explored in future studies.

Conclusions

This study has revealed that knowledge concerning product related services and usability patterns are more difficult to share between user and producer, than direct product functionality issues. Further, the analysis shows a significant effect of communication face-to-face and direct across locations on users knowledge sharing ability. Notable was that communication means across space but direct in time had a higher effect than face-to-face interactions. This indicates that the means to communicate directly and thereby the ability to reflect and obtain feedback when things occur is important to knowledge sharing between user and producer.

Managerial implications

Late stage network partners in the Pharmaceutical industry are primarily perceived as providers of concrete and pre-defined information concerning the clinical trials. However, the primary down-stream network partner, the medical sites, is highly qualified knowledge workers whom posses in-depth knowledge about the product and the related services and usability issues through their extensive integration in the down stream process. Users well-defined role in down-stream development may prevent the producer from tapping knowledge, which go beyond the issues and tasks medical users are expected to perform. The results indicate that pre-defined user roles may limit industry to optimally utilize the potential knowledge from users. Therefore, when highly skilled users are integrated in high-tech product testing processes, managers should consider the competences gained beyond the expected outcome of product functionality testing. An optimization of the utilization of users knowledge gained in product testing could thereby strengthen the product functionality, design and market launch, and potentially create spin-off products. Incorporating systems to utilize user input on a broader scale is therefore recommended in the planning of product testing in late stage development. In the design of the testing process managers should also consider the importance of direct interaction with the user, and here especially directly in time with the many global sites. Establishing good communication means where users can communicate with the producers as things occur can stimulate knowledge transfer concerning both product functionality and related services and usability issues.

Limitations and future research directions

Applying the Rasch scale model have supplied this study with several opportunities in relation to the research question, but also represents some limitations. A challenge to Rasch scale modeling is the construct and application of item measures. The individual items measured in relation to persons (data ID measures) needs to be constructed with continuity, and also representing the overall topic area to a satisfactory degree (Bond and Fox, 2001). This can create some challenges in the reliability of the continuum spread of the Rasch scale output. The data collection in this study has aimed at a high level of continuity in the items, by generating parallel questions and answer options, which have meet the limitation of reliability of scale items in the Rasch method. However, the spread of the items in relation to the person IDs represent some under-identification in the model. This is considered in the

conclusions of the study, which is kept on the level of differentiating between the two defined groupings; Managerial issues, and clinical issues. We suggest, that future research focus on expanding the scale of items, which can generate conclusions about specific management issues, individually and in relation to each other. It is relevant to explore further, which specific management issue areas users generate knowledge about, and how this knowledge is utilized by producers and further integrated in the production processes.

The Rasch scale model has proven to be beneficial in exploring issues in management research, and we therefore suggest that this approach is further developed for innovation management studies.

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